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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/645,556 | 08/25/2000 | Bernward Scholkens | 02481.1702 | 3278 |

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/645,556

Applicant(s)

SCHOLKENS ET AL.

Examiner

Jennifer Kim

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 6, 7, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 6, 7, 18, 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/9/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on October 16, 2003 have been received and entered into the application.

Action Summary

The rejection of claims 4, 6-7 and 18-19 under 35 U.S.C. 112, first paragraph is hereby expressly withdrawn in view of Applicant's amendment.

The rejection of claims 4, 6-7 and 18-19 under 35 U.S.C. 112, second paragraph is hereby expressly withdrawn in view of Applicant's response.

Claim 4 of record rejected under 35 U.S.C. 103 (a) over Gold et al. (U.S. Patent No. 4,587,258) in view of The Merck Manual, all of record is maintained for the reasons stated in the previous office action.

Claims 6-7 and 19 of record rejected under 35 U.S.C. 103 (a) over Gold et al. (U.S. Patent No. 4,587,258) and The Merck Manual, and further in view of Maclaughlan et al. (WO 96/24373), all of record is maintained for the reasons stated in the previous office action.

Claims 4 and 18 of record rejected under 35 U.S.C. 102 (b) over Allen et al. of record is maintained for the reasons stated in the previous office action.

Response to Arguments

Applicants' arguments filed on October 9, 2003 have been fully considered but they are not persuasive. Applicants argue that those skilled in the art understood that the treatment of hypertension itself would not necessarily reduce the risk of the onset of CHF since other factors, for instance acute myocardial infarction, can also cause CHF. This is not persuasive because hypertension is one of the contributing factor of CHF as taught by Merck Manual. Therefore, one of ordinary skill in the art would have been motivated to employ an ACE inhibitor in a method of reducing the risk of onset of CHF by treating hypertension which is an underlying cause of CHF, thereby reducing the risk of onset of CHF. Applicants next argue that there is doubts remained even though angiotensin converting enzyme inhibitors were already known to be useful for the treatment of hypertension. This is not persuasive because ACE inhibitors are well known and commercially available (e.g. ramipril) and approved by the FDA for the treatment hypertension and it is well-known by Gold et al. that ACE inhibitors' beneficial effects is not limited only through their action of functionally impaired cardiac muscle as alleged by Applicants. Applicants argue Allen does not disclose the prevention of CHF and does not even appear to discuss the details of any effects of ramipril on cardiac function generally. This is not persuasive because Allen utilizes same active agent, same dosage amount, to a same subject (patient) as set forth by Applicants' claim 4, therefore an effect of reducing the risk of onset of CHF would be inherent of cited reference as well as applicants' method of reducing the risk of onset of CHF in a patient not previously having CHF and who has an essentially maintained heart function in a

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normotensive patients treated by Allen. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of April 9, 2003 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
June 22, 2004